REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 37 and 39 have been amended herein. It will be seen that the amendments to claims 37 and 39 are fully supported in the as-filed specification from the following:

- contains at least 1 wt.% of granules suitable for use in foodstuffs (page 6, lines 21-22)
- contains one or more particulate bread improving ingredients selected from the group consisting of emulsifiers, oxidoreductants, acidulants, salt, sugars, flour, yeast, protein, dairy ingredients and fat; said granules and the bread improving ingredients together constituting at least 60% of the bread improver composition by weight of dry matter (paragraph bridging pages 13 and 14)
- the functional ingredients are selected from the group consisting of enzymes, oxidoreductants and combinations thereof (page 9, lines 21-22).
- the agglomerate of non-lipophilic particles and discrete continuous phase represents 50-90 wt.% of the granules (page 8, lines 17-18)
- the agglomerate formed by the non-lipophilic particles and the discrete continuous phase contains not more than 70 wt.% of said non-lipophilic particles and at least 30 wt.% of said discrete continuous phase (page 8, lines 19-20)

35 U.S.C. § 103

The Examiner has rejected claims 37-41 under 35 U.S.C. 103(a) as unpatentable over Sharma (US 4,797,288) in view of Fuglsang (US 2002/0094367). This rejection is traversed.

Claim 37

Amended claim 37 defines a method of preparing a dough, said method comprising adding a bread improver composition that contains at least 1 wt.% of encapsulated granules in combination with one or more particulate bread improving ingredients selected from the group consisting of emulsifiers, oxidoreductants, acidulants, salt, sugars, flour, yeast, protein, dairy ingredients and fat. Furthermore, amended claim 37 now recites that the granules and the bread improving ingredients together constitute at least 60% of the bread improver composition by weight of dry matter.

Sharma fails to disclose a method of preparing a dough in which a bread improver composition is added, let alone a method of preparing a dough in which a bread improver composition is employed that contains one or more particulate bread improving ingredients besides the encapsulated granules. Sharma does mention the use of delivery systems in baked goods (column 2, line 47 and column 8, lines 32-33). However, in both passages "baked goods" is referred to as a product category that is different from food products, pharmaceutical preparations, beverages, tobacco and proprietary products. Even if it is assumed, that "baked goods" refers to bakery food products, this does not imply that the delivery system is to be employed in a bread improver composition, let alone that it is to be used in such a bread improver composition in combination with the one or more of the particulate bread improving ingredients specified in claim 37, as amended.

Claim 37 further recites that the non-lipophilic particles contain at least 0.1 wt.% of one or more functional food ingredients selected from the group of enzymes and oxidoreductants. Sharma does not contain any teaching or disclosure of enzymes or oxidoreductants. In contrast, Sharma teaches granules containing non-lipophilic particles

in the form of a drug, a sweetener or a flavouring agent (column 1, lines 13-14; column 8, lines 25-27)

Applicants note that some of the data provided in the Sharma reference with regard to the composition of the delivery system is confusing. Hence, Applicants believe that a closer look at this reference is warranted.

Sharma provides a delivery system comprising (see column 2, lines 19-30):

(a) a drug; and

(b) a hydrophobic matrix comprising an emulsifier, a high melting point edible material and at least one glyceride.

Sharma further describes delivery systems in which the components (a) and (b) have been coated with an out coating that preferably consists of a blend of hydrogenated palm oil and paraffin wax (column 7, lines26-29).

Below, Applicants have recited the passages of Sharma that provide quantitative information about the composition of the delivery system:

1) Column 3, lines 35-37: *The emulsifier is present in amounts of 0.5 to about 20% and preferably about 3 to about 5% by weight of the delivery system*

2) Column 4, lines 37-41: *The edible fatty acid or wax materials are employed in the instant delivery systems in amounts of about 61% to about 95% by weight of the delivery system, preferably in amounts of about 63% to about 90% and most preferably in amounts of about 66% to about 80%*

3) Column 5, lines 3-6: *The glycerides are present in amounts of about 0.5 to about 30% by weight of the delivery system. Preferably the glyceride is used in amounts of about 0.5 to about 7% and most preferably about 1% to about 3%*

4) Column 5, lines 23-29: *The weight percent of the drug or its acid addition salt thereof, based on the weight of the coating matrix from about 1% to about 75%;*

preferably about 5% to about 30%; more preferably about 10% to 20%; and most preferably about 15% to about 19%, which amounts will vary depending upon the therapeutic dosage permitted

5) Column 6, lines 50-53: *The drug is present in the delivery system in amounts of about 50 to about 99% by weight; preferably about 65 to about 85%; and most preferably about 70 to about 80%*

6) Column 8, lines 15-19: *It has been determined that using the exterior coating in amounts of about 200 to about 400% by weight of the agglomerate maximizes the taste masking benefits with the controlled release benefits. Use of the exterior coating in less than amounts of about 30% by weight of the core (drug) material.*

Applicants note that the terminology "by weight of the delivery system" in passages 1) to 3) above refer to delivery system that is defined by the drug and the hydrophobic matrix, i.e. it does not include the external coating. In passage 4) the "coating matrix" is deemed to be synonymous with the hydrophobic matrix.

These interpretations find support in the fact that the most preferred ranges for the drug and the hydrophobic matrix components add up to 100% as demonstrated in the following table:

	Most preferred range (% by weight of agglomerate)	**Average**
Emulsifier	3-5	4
Edible fatty acid/wax	66-80	73
Glycerides	1-3	2
Drug	15-19	17

As regards passage 5), one might be inclined to assume that the amounts recited therein are to be construed as percentages by weight of the agglomerate constituted by the drug and the hydrophobic matrix. However, clearly this is not what is meant as such interpretation is irreconcilable with the percentages presented in passage 4), the examples and the claims. Hence, below we have taken the drug concentrations mentioned in passage 4) as a starting point.

The wording "by weight of the agglomerate" in passage 6) should be construed as "by weight of the delivery system composed of the drug and the hydrophobic matrix.

If the above interpretations are applied, it can be concluded that Sharma teaches delivery systems having the following compositional features:

	Sharma		
	Description	**Examples One to Six**	**Example Seven**
Hydrophobic matrix % (w/w) of agglomerate	61.5-99	62-96	62
• *emulsifier*	*0.5-20*	*0.5-20*	*17*
• *edible fatty acid/wax*	*61-95*	*61-80*	*20*
• *glycerides*	*0.5-30*	*0.5-30*	*25*
Drug as % (w/w) of agglomerate	~~1-75~~ 1-38.5 #	~~4-40~~ 4-38 #	38
Exterior layer as % (w/w) of agglomerate	200-400	?	n.a.
Hydrophobic matrix as % (w/w) of granule	*Calculated 12.3-33*	?	
Drug as % (w/w) of granule	*Calculated* 0.2-12.8	?	
Exterior layer as % (w/w) of granule	66.7-80		

As is evident from the above table, the drug concentration range of 1-75% by weight of the agglomeratre is unduly broad. Since the drug and the hydrophobic matrix together constitute the agglomerate, and since the emulsifier and the edible fatty acid/wax component are necessarily present in the hydrophobic matrix, it is self-evident that the drug concentration within the agglomerate has to be in the range of 1-38.5 wt.%

Thus, it can be concluded that in terms of composition the granules defined in claim 37 when compared to the delivery systems broadly described by Sharma as follows;

	Claim 37	**Sharma**
Exterior layer as % (w/w) of granule	10-50 wt.%	66.7-80 wt.%
Discrete phase as % (w/w) of agglm.	≤70 wt.%	61.5-99 wt.%
Non-lipoph. particles as % (w/w) of agglm.	≥30 wt.%	1-38.5 wt.%

From this table it can be concluded that Sharma fails to teach granules comprising an exterior layer that represents no more than 50 wt.% of the granule. In addition, although there is a small overlap between the individual concentration ranges given for the discrete phase and the non-lipophilic particles, the preferred ranges of Sharma (15-19 wt.% drug and 81-85 wt.% of hydrophobic matrix) clearly teach away from agglomerates wherein the non-lipophilic particles and discrete phase are present a weight ratio of at least 30:70.

As regards the exterior layer, the Examiner observes: "*Sharma suggest that the exterior coating may be used in amounts as low as 30% of the weight of the core material (col. 8, lines 10-21)*". Applicants ***strongly disagree*** with this assertion. In column 8, lines 10-21 of Sharma the following statement is made:

The taste masking and delayed hydration characteristics of the delivery system is dependent not only on the completeness of the surface area coated, but on the thickness

of the coating. A balance should be maintained such that too thick a coating is not used so as to prevent proper release of the drug. It has been determined that using the exterior coating in amounts of about 200 to about 400% by weight of the agglomerate maximizes the taste masking benefits with the controlled release benefits. Use of the exterior coating in less than amounts of about 30% by weight of the core (drug) material.

What ensues from this passage is that Sharma et al. teach that the coating should not be too thick to prevent proper release of the drug and that it should have an adequate thickness to "*maximize the taste masking benefits with the controlled release befits*". These considerations lead Sharma et al. to the recommendation to use "*the exterior coating in amounts of about 200 to about 400% by weight of the agglomerate*".

The last sentence of the cited paragraph clearly has been garbled up. Linguistically this sentence is not a proper sentence and it is clear that it is incomplete. In Applicants' view the Examiner's interpretation that this incomplete sentence suggests to use an exterior coating in amounts as low as 30% of the weight of the core material is made with the benefit of hindsight. Furthermore, Applicants note that the Examiner's interpretation appears to be irreconcilable with the recommendations provided earlier in the same paragraph of Sharma.

Hence, Applicants submit that Sharma et al. fails to teach or suggest the following features of amended claim 37:

A method of preparing a dough comprising adding a bread improver composition containing:

- one or more particulate bread improving ingredients selected from the group consisting of emulsifiers, oxidoreductants, acidulants, salt, sugars, flour, yeast, protein, dairy ingredients and fat;
- granules comprising
    - 50-90 wt.% of an agglomerate containing 10-70 wt.% of the plurality of the non-lipophilic particles and 30-90 wt.% of the discrete continuous phase;

- 10-50 wt.% of an exterior lipophilic layer;

wherein the liphophilic particles contain at least 0.1 wt.% of one or more functional ingredients selected from the group consisting of enzymes and oxidoreductants.

The Examiner has relied on Fugelsang and has made the following observations with respect to this reference: "*Sharma discloses incorporating this composition into baked goods (column 8, lines 31-32) but fails to explicitly disclose the use of the granules as a bread improver. However, Fuglsang, like Sharma discloses functional ingredients for incorporation into foodstuffs which are coated with a lipid substance in order to control the release of the functional ingredient into the surrounding foodstuff ([0017]-[0029]). The functional ingredients disclosed in Fuglsang are enzymes, which can be used as dough conditioners or improvers ([0004]-[0005]). Given the teachings of Sharma and Fuglsang, one having ordinary skill in the art at the time of the invention would have found it obvious to modify the lipid coated, controlled release functional food ingredient of Sharma by incorporating enzymes as the functional ingredient as in Fuglsang, as the coating of Sharma is effective for allowing the artisan to control the time of release of the functional ingredient, which is a goal shared by Fuglsang*".

Applicants respectfully disagree with the Examiner and traverse the Examiner's assumption that at the time of the present invention a person of ordinary skill in the art would have been motivated to combine Sharma and Fuglsang.

The Sharma patent is titled "NOVEL DRUG DELIVERY SYSTEM" and that it has been assigned to international class A61K 9/46 and A61K 47/00 (A 61K = PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES) and to US classes 424/476; 424/70; 424/498; 424/502 (Class 424 = DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS).

The Fuglsang application is titled: "DOUGH COMPOSITION" and that it has been assigned to international class A21D 2/00 (A21D = TREATMENT, e.g. PRESERVATION, OF FLOUR OR DOUGH FOR BAKING, e.g. BY ADDITION OF

MATERIALS; BAKING; BAKERY PRODUCTS; PRESERVATION THEREOF) and US classes 426/549; 426/94 and 426/61 (Class 426 = FOOD OR EDIBLE MATERIAL: PROCESSES, COMPOSITIONS, AND PRODUCTS).

As is clear from the above referenced titles and patent classifications, Sharma and Fuglsang basically relate to vastly different and non-analogous technical fields. Fuglsang mentions the use of the delivery systems described therein in baked goods, but no further information is provided about such use. Applicants submit that the mere mentioning of the possibility of using delivery systems of Sharma in bakery goods, given that these systems have primarily been designed as drug delivery systems, would not have incited or caused a person of ordinary skill to combine Sharma with Fuglsang.

Even if a person of ordinary skill in the art would have combined Sharma and Fuglsang, Applicants traverse the Examiner's implicit reasoning that Fuglsang would have motivated such a skilled person:

- to combine the delivery system of Sharma with one or more particulate bread improving ingredients selected from the group consisting of emulsifiers, oxidoreductants, acidulants, salt, sugars, flour, yeast, protein, dairy ingredients and fat; and

- to reduce the amount of exterior lipophilic layer from 66.7-80 wt.% from 10-50 wt.%.

Fuglsang teaches a method for preparing a dough composition, comprising the addition of one or more enzymes encapsulated or coated with a lipid substance. Fuglsang describes two types of enzyme preparations: Enzyme Vesicles ([0095]-[0105]) and Coated Enzymes ([0106]-0123]). The Enzyme Vesicles are enzymes encapsulated by a multilamellar bilayer of lipid substance (phosphoglyceride) and are employed in a dough mixture in the from of an aqueous dispersion of these vesicles. The Coated Enzymes comprise an enzyme-containing core and a coating of a lipid substance.

Fuglsang is totally silent as to the amount of lipid coating that is to be employed in the Coated Enzymes. Also, the examples of Fuglsang do not provide any examples of Coated Enzymes. Consequently, Applicants conclude that at the time of the present

invention Fuglsang would not have motivated a person of ordinary skill in the art to reduce the amount of the exterior layer in the drug delivery systems of Sharma with a reasonable expectation that the resulting delivery system, if employed to deliver bakery enzyme, could suitably be used as a bread improving composition in dough. Thus, the subject matter recited in claim 37 is deemed to distinguish over the combined teachings of Sharma and Fuglsang. Accordingly, the rejection under 35 USC § 103(a) has been overcome and should be withdrawn, since the Examiner has failed to establish a case of *prima facie* obviousness by a preponderance of the evidence.

Claim 38

Claim 38 defines a dough or a batter comprising between 0.01 and 5 wt.% of the granules as defined in claim 37. As explained herein before, it is Applicants' view that even when taken in combination, Sharma and Fuglsang would not have led a person of ordinary skill in the art to granules comprising an agglomerate and an exterior coating that represent 10-50 wt.% of the granules. Consequently, the subject matter recited in claim 38 distinguishes over the combined teachings of the references.

Claim 39

Amended claim 39 recites a method of manufacturing a composition comprising at least 1 wt.% of granules as defined in claim 37. Hence, what has been said above in relation to claim 37 equally applies to claim 39. Thus, claim 39 also distinguishes over the combination of art applied by the Examiner.

Claims 40 and 41, which depend from claim 39, which depends from claim 37 also distinguish over the combined references for the reasons set forth above.

The issuance of a Notice of Allowance is respectfully solicited.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

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